JAN 24 2012

510(k) Summary of
Safety and Effectiveness in accordance with 21 CFR 807.92
Honeywell HomMed Genesis™ Touch System

(a) (1) Submitter: Honeywell HomMed, LLC

Address: 3400 Intertech Drive, Suite 200
Brookfield, Wisconsin 53045

Corporate Contact: Greg Lillegard, Director of Quality
Honeywell HomMed, LLC

Telephone: Ph: (262) 252-262-6062
Fax: (262)252-262-6119

Establishment Registration #: 3004183721

Submission Contact: Claudia Jackson, Regulatory Affairs Specialist
Honeywell HomMed, LLC
3400 Intertech Drive, Suite 200
Brookfield, Wisconsin 53045
Ph: (262) 252-5838
Fax: (262) 252-6119
Date: 09/27/2011

(2) Trade Name: Honeywell HomMed Genesis Touch System

(3) Predicate Device: Honeywell HomMed Genesis DM, K101242

Common Name: Patient Vital Signs Monitor

Classification Name:

Regulation Number	Product Code	Classification Name	Device Class
870.2910	DRG	Radiofrequency Physiological Signal Transmitter and Receiver	II
Medical device product codes also supported by Genesis Touch System by means of separate medical devices			
870.1130	DXN	Noninvasive Blood Pressure Measurement System	II
880.2700	FRI	Patient Weight Scale	I
870.2700	DQA	Oximeter	II

(4) Device Description:

The Honeywell HomMed Genesis Touch™ Retrospective Physiological Monitoring System uses text and voice prompts to help the user acquire vital signs information. Once all data is collected, it is forwarded at the user's discretion, as a data packet to a central viewing station for retrospective review by a healthcare provider. The Genesis Touch Retrospective Physiological

Monitoring System is intended for use with adult and pediatric patients over twelve years of age. The Genesis Touch Retrospective Physiological Monitoring System is not intended for emergency use or real-time monitoring.

(5) Indications for Use:

The Honeywell HomMed Genesis Touch Retrospective Physiological Monitoring System is designed to retrospectively monitor vital signs. Vital signs include noninvasive blood pressure, pulse oximetry, pulse rate, weight and manually entered temperature. The Genesis Touch Retrospective Physiological Monitoring System collects, displays and transmits vital signs measurements captured from commercially available FDA cleared wireless medical devices designed for home use. Collected measurement data from the Genesis Touch System can be transmitted via a communication module to a central viewing station where the data can be viewed and analyzed by a healthcare professional.

The Genesis Touch Retrospective Physiological Monitoring System is intended for home use by adult and pediatric patients over twelve years of age or in a healthcare related environment by healthcare providers. The Genesis Touch Retrospective Physiological Monitoring System is not intended for emergency use or real-time monitoring and does not have auditory or visual alarms for out-of-limit parameters.

(6) Technological Characteristics:

Genesis Touch Retrospective Physiological Monitoring System (Genesis Touch System) is substantially equivalent to the predicate device, Honeywell HomMed Genesis DM, K101242 as an application of a dedicated software/hardware platform, with the function of data collection and display from standard parameters such as interfaceable peripheral medical device types, data transmission, and communication to the central server.

Genesis Touch Retrospective Physiological Monitoring System is a proprietary software application that operates on a dedicated commercially available off the shelf (COTS) touch screen tablet with the minimum performance specifications consistent with typical tablet computer hardware and equipment specifications.

(b) Performance Data:

The Genesis Touch System is a proprietary software application running on a dedicated tablet platform with minimum performance specifications consistent with typical tablet computer hardware and equipment specifications. Similar to the dedicated software/hardware platform functionality of the Genesis DM (K101242) operating system, the Genesis Touch application restricts, or "locks down", the system's functionality such that the user cannot install other programs, nor use the device for any other purpose other than the intended use.

Genesis Touch System is substantially equivalent to the predicate device, Honeywell HomMed Genesis DM, K101242, as a dedicated software/hardware platform application, for user vital signs data collection and display from noninvasive medical device peripherals, as well as communication and transmission of the data to a central server for retrospective review.

Risk based verification and validation testing based on FDA guidance "General Principles of Software Validation; Final Guidance for Industry and FDA Staff and in accordance with FDA's "Guidance for Industry and FDA Staff: Guidance for the Content of Premarket Submissions for Software Contained on Medical Devices" was performed to ensure that the data is collected and transmitted as intended to the central server.

The Honeywell HomMed Genesis Touch System complies with the following voluntary standard:

- IEC 62304 Medical Device Software – Software Life Cycle Processes

Due to the equivalent indications for use of this system to its predicate, no clinical tests were performed as part of the performance testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JAN 24 2012

Honeywell HomMed
c/o Ms. Claudia Jackson
3400 Intertech Dr., Suite 200
Brookfield, WI 53045

Re: K112858
Trade/Device Name: Genesis Touch System
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency Physiological Signal Transmitter and Receiver
Regulatory Class: Class II
Product Code: DRG
Dated: January 9, 2012
Received: January 10, 2012

Dear Ms. Jackson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K112858

Device Name: Honeywell HomMed Genesis Touch System

Indications For Use:

The Honeywell HomMed Genesis Touch Retrospective Physiological Monitoring System is designed to retrospectively monitor vital signs. Vital signs include noninvasive blood pressure, pulse oximetry, pulse rate, weight and manually entered temperature. The Genesis Touch Retrospective Physiological Monitoring System collects, displays and transmits vital signs measurements captured from commercially available FDA cleared wireless medical devices designed for home use. Collected measurement data from the Genesis Touch System can be transmitted via a communication module to a central viewing station where the data can be viewed and analyzed by a healthcare professional.

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Prescription Use _____ AND/OR Over-The-Counter Use __X____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K112858